



MOLECULAR AND CLINICAL GENETICS PANEL
AGENDA**March 26, 2014****Molecular and Clinical Genetics Panel****Epigenomics AG****Epi proColon[®]****Hilton Washington DC North/Gaithersburg**

On March 26, 2014, the committee will discuss, make recommendations and vote on information related to the premarket approval application sponsored by Epigenomics AG for the Epi proColon. The Epi proColon test is a qualitative *in vitro* diagnostic test for the detection of methylated Septin 9 DNA in plasma derived from patient whole blood specimens. Methylation of the target Septin 9 DNA sequence has been associated with the occurrence of colorectal cancer (CRC). The test is indicated to screen patients for CRC who are defined as average risk for CRC by current screening guidelines. The Epi proColon test is not intended to replace colorectal screening by colonoscopy. Patients with a positive Epi proColon test result should be referred for diagnostic colonoscopy. The Epi proColon test results are intended to be used in conjunction with the physician's assessment of history, other risk factors, and professional guidelines.

8:00 a.m.	Call to Order Introduction of Committee Conflict of Interest Statement	Chairperson Jamie Mae Waterhouse, M.B.A. Designated Federal Officer
8:15 a.m.	Sponsor Presentation	
9:30 a.m.	Sponsor Q&A	
9:45 a.m.	Break	
10:00 a.m.	FDA Presentation	
11:15 a.m.	FDA Q&A	
11:30 p.m.	Lunch	
12:30 p.m.	Open Public Hearing	
1:30 p.m.	Panel Deliberations	
2:15 p.m.	Break	
2:30 p.m.	FDA Questions to the Panel	
4:00 p.m.	FDA and Sponsor Summations	
4:30 p.m.	Panel Vote	
5:00 p.m.	Adjournment	

* **Open Public Hearing** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.